UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, Plaintiff, v. ELI LILLY AND COMPANY, IMCLONE LLC and BRISTOL-MYERS SQUIBB COMPANY, Defendants.	)	Civil Action No. 2:15-cv-06133-WB

JOINT REPORT OF RULE 26(f) MEETING AND PROPOSED DISCOVERY PLAN

In accordance with Federal Rule of Civil Procedure 26(f), counsel for Plaintiff Trustees of the University of Pennsylvania ("Penn") and Defendants Eli Lilly and Company ("Eli Lilly"), Imclone LLC ("ImClone"), and Bristol-Myers Squibb Company ("BMS") (collectively "Defendants") conferred telephonically on January 26, 2016, and submit to Chambers the following report of their meeting for the Court's consideration:

I. DISCUSSION OF CLAIMS, DEFENSES, AND RELEVANT ISSUES

A. Plaintiff's Summary of Case[1]

This is an action for patent infringement brought by Penn against Defendants regarding inventions claimed in U.S. Patent No. 7,625,558 ("the '558 patent" or "Patent-in-Suit"). The inventors of the '588 patent developed novel therapies for treating certain types of cancerous

[1] Plaintiff disagrees with the tone and allegations set forth in Defendants' portion of this report, but in keeping with the Court's order to concisely set forth the factual background of the case, Plaintiffs will not utilize this 26(f) report to respond on a point-by-point basis.

tumors (erbB protein-mediated tumors) using a specific type of antibody (an anti-erbB antibody) followed by anti-cancer radiation therapy. Anti-erbB antibodies inhibit the formation of erbB protein dimers and arrest the growth of cancer cells that rely on such dimers for cell division. Prior to the invention of the '558 patent, it was known that anti-cancer radiation works on dividing cells. Therefore, one of ordinary skill in the art would not have believed that prior treatment with a cytostatic agent—one that stops cells from dividing—would enhance a patient's response to radiation therapy.

The asserted claims of the Patent-in-Suit cover methods of treating a patient suffering from an erbB protein-mediated tumor by first administering an antibody with erbB inhibitor properties to the patient and then exposing the patient to anti-cancer radiation. Cetuximab, sold by Defendants under the trade name Erbitux,[2] is an anti-erbB antibody that inhibits the formation of erbB protein dimers, and is used for the treatment of certain types of cancer. In 2006 Erbitux was approved by the United States Food and Drug Administration ("FDA") for the treatment of locally or regionally advanced squamous cell carcinoma of the head and neck (an erbB protein-mediated cancer also known as "locally or regionally advanced SCCHN") in combination with radiation therapy.

Based on publicly available information, Plaintiff believes that Defendants manufacture, market, sell, and distribute Erbitux with an FDA-approved label and package insert that instructs physicians to treat locally or regionally advanced SCCHN by administering Erbitux followed by administering anti-cancer radiation therapy. Plaintiff believes that Defendants indirectly infringe the '558 patent by actively encouraging, instructing, and inducing physicians to practice the claimed methods of the Patent-in-Suit. Defendants have alleged that they do not infringe the

[2] Erbitux was developed and commercialized by Defendants ImClone and BMS. ImClone subsequently became a wholly-owned subsidiary of Eli Lilly.

'558 patent, and that the '558 patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112, and/or 116. Penn disagrees with the Defendants' non-infringement and invalidity allegations.

Defendants also allege that the relief sought by Penn is unavailable due to laches, waiver, and/or equitable estoppel. Penn disagrees with those allegations, and will respond to these arguments at the appropriate time, except for noting the following. Defendants' portion of this report implies that Penn unreasonably and inexcusably delayed in asserting the '558 patent because it filed the Complaint in November 2015. But Defendants fail to mention that Penn and Defendant Lilly entered into a stand-still agreement on July 29, 2015 which expired just prior to the filing of Penn's Complaint. The stand-still agreement suspended all applicable statutes of limitations and further provided that neither party would be prejudiced by entering into licensing discussions.

Concurrently with their Answer (D.N. 22), Defendants moved to dismiss Plaintiff's allegation that Defendants infringe claims 32-40 of the '558 patent (D.N. 21). As will be explained more fully in Plaintiff's opposition brief, any multiple dependency errors in such claims can easily be corrected by this Court, and therefore Plaintiff's allegation of infringement of those claims should not be dismissed.

A day prior to answering the instant complaint, Defendant Eli Lilly filed a petition for *inter partes* review ("IPR") of the '588 patent with the U.S. Patent and Trademark Office, Patent Trial and Appeal Board ("PTAB").[3] Defendants have also moved to stay this case pending resolution of the IPR. (D.N. 23).[4] Plaintiff disagrees that the case should be stayed at this early

[3] Docketed as IPR2016-00458.

[4] In its summary below, Defendants assert that both the U.S. prosecution of continuation applications and European opposition proceedings are relevant. These arguments are red herrings and Plaintiff will respond in its opposition to Defendants' motion to stay the litigation.

stage, even before the PTAB has decided whether the petition demonstrates a reasonable likelihood of Eli Lilly prevailing on at least one claim.

B. Defendants' Summary of Case

Contrary to what Penn alleges, at the time Penn filed its patent applications, there was nothing novel or non-obvious about the '558 patent's proposal to use anti-erbB antibodies with radiation to treat certain types of cancer; the use of such antibodies to enhance the effect of radiation was known well before the '558 patent was filed. Defendants believe that the asserted claims of the '558 patent are invalid for failing to meet all of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, and 116.

ImClone began pre-clinical development of cetuximab (subsequently trademarked as Erbitux) when it acquired rights to the antibody in 1993. In 1994, ImClone filed an Investigational New Drug (IND) Application with FDA seeking authorization to administer the experimental antibody to humans. By 1995, ImClone had partnered with researchers at the University of Alabama at Birmingham to conduct clinical trials to demonstrate the effectiveness of cetuximab when combined with radiation therapy. The University of Alabama scientists presented their results at the 1996 Annual Meeting of the American Association for Cancer Research[5]—two years before Penn filed its first provisional patent application. At least two other groups were also doing research in this area and published their results in 1996: a team of

[5] Saleh *et al.*, In vitro *and* in vivo *evaluation of the cytotoxicity of radiation combined with chimeric monoclonal antibody to the epidermal growth factor receptor*, 37 Proc. Am. Assoc. Cancer Res. 612, Abstract No. 4197 (1996).

scientists at the University of California, Davis[6] and a different group of researchers at U.C. Davis, together with their colleagues at the New York Hospital Medical Center of Queens.[7]

Both the United States Patent and Trademark Office ("USPTO") and the European Patent Office have found that Penn's alleged invention was obvious in light of the work of the scientists at the University of Alabama at Birmingham, U.C. Davis, and the New York Hospital Medical Center. The USPTO has repeatedly rejected claims in patent applications claiming priority to the '558 patent as being obvious over this prior art. The European Patent Office revoked Penn's European counterpart patent for similar reasons.

Eli Lilly has filed a petition for *Inter Partes* Review of the '558 patent. In the petition, Eli Lilly presents conclusive evidence (including the research described above) that 26 of the 35 claims asserted in this case are obvious. Defendants have filed a Motion to Stay this litigation in light of Eli Lilly's petition.

Defendants have also filed a Motion to Dismiss, presenting evidence that the remaining nine asserted claims in this case are facially invalid. The petition for *Inter Partes* Review, combined with the Motion to Dismiss, should establish that all of the asserted claims of the '558 patent are invalid, thereby resolving all issues raised in this litigation.

Separately, Defendants will establish that scientists at ImClone, alone or in combination with researchers at the University of Alabama at Birmingham, invented and practiced the methods claimed in the '558 patent prior to the alleged invention at the University of Pennsylvania. The claims of the '558 patent are therefore invalid under 35 U.S.C. § 102(g).

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[6] DeNardo *et al.*, *Importance of temporal relationships in combined modality radioimmunotherapy of breast carcinoma*, 80 Cancer 2583–90 (1997).
[7] Balaban et al., *The effect of ionizing radiation on signal transduction: antibodies to EGF receptor sensitize A431 cells to radiation*, 1314 Biochim. Biophys. Acta 147–156 (1996)

Defendants will also present arguments that the claims of the ’558 patent are invalid under 35 U.S.C. § 112. The claims are directed to methods of treating cancer by administering an antibody followed by radiation. These claims are overly broad, and purely functional. They preempt all antibodies that function in the claimed method. This overly broad scope extends well beyond the contribution of the inventors. The Defendants will also establish that these overly broad claims lack written description and are not enabled.

Finally, even if the claims of the ’558 patent are found not to be invalid, Penn cannot prove that any of the Defendants have infringed the ’558 patent. During the prosecution of the ’558 patent, the inventors were forced to make a variety of concessions and to narrow their claims in order to distinguish their alleged invention from the prior art. As a result, the use of Erbitux does not infringe any of the claims of the ’558 patent.

II. INITIAL AND INFORMAL DISCLOSURES

The parties will exchange information required by Fed. R. Civ. P. 26(a)(1) and paragraphs 2–4 of the Court’s Draft Order Governing Electronic Discovery (D.N. 18-1) on February 1, 2016.

III. FORMAL DISCOVERY

The anticipated formal discovery needs of the parties at this time are stated without limiting the scope of information sought by the parties in discovery and without waiver of either party’s right to object to any particular discovery request.

A. Plaintiff’s Discovery Needs

Plaintiff will require discovery from Defendants on their contentions, declaratory judgment counterclaims, and defenses concerning the Patent-in-Suit. Plaintiff will also require discovery from Defendants related to damages. Plaintiff may also require discovery from

unknown third parties relating to: (1) the actual use of Erbitux by physicians; (2) possible secondary considerations of nonobviousness of the Patent-in-Suit; and (3) prior art status (depending on Defendants' invalidity allegations).

To support its claims, Plaintiff will seek discovery on at least the following topics: the research and development of Erbitux followed by radiation therapy; commercial and regulatory review and approval of the administration of Erbitux followed by radiation therapy for treatment of locally or regionally advanced SCCHN and the associated versions of the Erbitux label and package insert; Defendants' marketing, distribution, sales and demonstrations of Erbitux, including Erbitux followed by radiation therapy; Defendants' pre-suit knowledge of the '558 patent; the use by health care practitioners of Erbitux followed by radiation therapy for treatment of locally or regionally advanced SCCHN; and relevant efficacy data, usage data, studies, and tutorials. Plaintiff will also seek discovery into: revenue received or paid by Defendants in connection with manufacturing, marketing, selling or using Erbitux; and the percentage of Erbitux (actual, estimated or projected) used with either anti-cancer radiation or locally or regionally advanced SCCHN as well as the revenue associated with that percentage of use. Plaintiff anticipates that it may need to seek other discovery in support of its claims as Defendants disclose the bases of their defenses thereto.

Additionally, Plaintiff expects to rely, in part, on expert opinion testimony to support its liability and damages case. Plaintiff also expects to file claim construction briefing, dispositive motions, and pretrial motions. Plaintiff proposes the schedule attached as Exhibit A, which incorporates detailed milestones that typically arise in a patent case, including an exchange of preliminary contentions and claim construction positions.

Plaintiff disagrees with Defendants that it is necessary to adopt the Local Patent Rules of either the Northern District of California or the District of New Jersey. As Defendants point out below, this is a straightforward patent case involving a single patent. Penn believes the schedule it proposes is appropriate for the case at hand and consistent with this Court's past case management practices.

Plaintiff proposes that it may serve a maximum of 30 interrogatories on each Defendant and Defendants collectively may serve a maximum of 30 interrogatories on Plaintiff. Plaintiff proposes that contentions be disclosed pursuant to the proposed schedule, and that any supplements or amendments to those contentions are due four weeks prior to the close of fact discovery. Plaintiff has already served an initial set of 11 interrogatories on each Defendant that are substantively identical. Plaintiff does not envision serving 30 distinct interrogatories on each Defendant.

Plaintiff disagrees with Defendants' discovery proposal to limit interrogatories to 20 per party, as it restricts Penn to less than the number contemplated by the Federal Rules of Civil Procedure and would unfairly prejudice Penn because Penn will have distinct discovery needs from each Defendant and, in contrast, Defendants (which are acting in concert in this litigation) largely will have common discovery needs from Penn. There is no need for Defendants to have up to 60 distinct interrogatories.

Plaintiff proposes that it may serve a maximum of 100 requests for admission on each Defendant and Defendants collectively may serve a maximum of 100 requests for admission on Plaintiff. There is no limit on any party for request for admission for admissibility or authenticity. Plaintiff disagrees with Defendants' proposal to limit requests for admission to 50 per side, including requests for admission for admissibility or authenticity. Requests for

admission are typically used to streamline the case and Plaintiff sees no benefit in departing from the Federal Rules of Civil Procedure and restricting such requests.

Plaintiff proposes that each side is limited to a total of 100 hours of taking testimony by deposition upon oral examination, excluding expert depositions. No witness shall be deposed in this case more than once unless by agreement of the parties or by order of the Court for good cause shown. Other than expert depositions related to claims construction, depositions shall not commence until document discovery is substantially complete.

B. Defendants' Discovery Needs

Given the likelihood that the USPTO will find the majority of the claims of the '558 patent to be unpatentable, Defendants believe that this case should be stayed pending the outcome of Eli Lilly's petition for *Inter Partes* Review. As explained in Defendants' pending Motion to Stay Pending *Inter Partes* Review (D.N. 23), Penn will not be prejudiced by a stay. Penn acknowledges that the allegedly infringing use of Erbitux was approved by FDA in 2006. *See supra* § I.A. Yet Penn waited until November 2015—nine years after FDA approval and nearly six years after the '558 patent issued—before filing suit.[8] Penn's delay in filing suit, combined with the fact that Penn is not a competitor to any of the Defendants and does not manufacture or sell any products that compete with Erbitux, negates any suggestion that Penn would be prejudiced by a six-month stay while the USPTO evaluates Eli Lilly's petition for *Inter Partes* Review. It therefore makes sense to stay the litigation before the parties are forced to engage in expensive and time-consuming discovery.

In the event that the Court denies Defendants' Motion to Stay, discovery should be governed by the local patent rules of the United States District Court for the Northern District of

[8] Penn notes that it entered into a standstill agreement with Eli Lilly for three and a half months. But Penn does say how it would be prejudiced by a stay.

California. The Northern District of California was the first court to adopt local patent rules, and its rules have served as the model for local patent rules adopted by other district courts across the country. The N.D. Cal. local patent rules provide a well-established set of rules governing the exchange of infringement and invalidity contentions as well as a detailed set of procedures for claim construction. Defendants' proposed schedule, outlined in Exhibit A, is based on the timeline established in the N.D. Cal. local patent rules.[9]

Defendants will require discovery on Penn's alleged invention of the methods claimed in the '558 patent, including, but not limited to, evidence of the conception of the claimed methods; evidence of the earliest reduction to practice of the claim methods; and evidence regarding the inventive contributions of each of the named inventors on the '558 patent as well as the contribution of other researchers at the University of Pennsylvania who were not named as inventors on the patent. Defendants will require discovery into the factual and legal bases for Penn's allegations that the use of Erbitux practices the claimed methods of the '558 patent. Defendants will also require discovery to determine the circumstances under which Penn learned of Erbitux and the reasons that Penn waited nearly six years from the date the '558 patent issued before filing this lawsuit. Defendants will require discovery into the factual and legal bases for any arguments Penn may raise as to why the claims of the '558 patent are not invalid over the prior art. Defendants will also require discovery into the prosecution of the '558 patent and related patent applications. Defendants will also require discovery into Penn's efforts to license or otherwise commercialize the '558 patent.

Defendants' oppose Penn's request to expand the number of interrogatories beyond that provided for in Fed. R. Civ. P. 33. *First*, this is a relatively straightforward patent case,

[9] In the alternative, Defendants propose that discovery be governed by the local patent rules of the United States District Court for the District of New Jersey.

involving only a single patent. Penn has not identified any facts or complications that would require additional interrogatories. In addition, under the N.D. Cal. local patent rules, the parties are required to provide detailed infringement and invalidity contentions, obviating the need for many contention interrogatories. Defendants therefore propose that Penn be permitted to serve no more than 20 interrogatories on each Defendant and that each Defendant be limited to serving 20 interrogatories on Penn.

Defendants oppose Penn's proposal that each side be allowed 100 hours of deposition time, excluding expert depositions. Rule 30 of the Federal Rules of Civil Procedure generally provides for each side to take 10 depositions. *See* Fed. R. Civ. P. 30(a)(2)(A)(i). Penn has not offered any reason to depart from that baseline. Defendants therefore propose that each side be allowed 70 hours of depositions, excluding expert depositions. In addition, Defendants see no reason to delay depositions until document discovery is substantially complete, as Penn has proposed. Penn's proposal would require that the deposition of all fact witnesses, including 30(b)(6) depositions of all parties as well as any third party deposition, be completed in a narrow 2 month window (under Plainitff's schedule) or 3 month window (under Defendants' schedule).

Defendants propose that each party be limited to 50 requests for admissions, including admissions of admissibility and authenticity.

Defendants propose that expert discovery be conducted according to the schedule outlined in Exhibit A.

IV. ELECTRONIC DISCOVERY

The parties shall cooperate to develop an electronic discovery protocol to govern the electronic discovery process and lessen the burden of producing electronic discovery. The parties are continuing to meet and confer to reach an agreed upon protocol for electronic discovery and

will submit the protocol, highlighting any remaining disputed issues, no later than January 29, 2016.

V. EXPERT WITNESS DISCLOSURES

The parties intend to disclose the identity of expert witnesses, exchange expert reports, and complete expert discovery in accordance with the attached proposed schedule.

VI. EARLY SETTLEMENT OR RESOLUTION

A. Plaintiff's Position

Prior to filing suit, Plaintiff and Lilly conducted negotiations over the course of multiple months in an attempt to resolve Plaintiff's claims against all three Defendants. No agreement was reached. Plaintiff is willing to discuss potential settlement at any stage of this litigation. However, formal mediation may be more fruitful after the parties have exchanged preliminary contentions or after claim construction. Plaintiff's counsel has explained this District's mediation rules to its client, including Local Rule 53.3.

B. Defendants' Position

Defendants are willing to discuss a potential settlement at any stage of this litigation. Defendants are amenable to formal mediation.

VII. TRIAL DATE

Each party's proposed trial dates are included in the attached proposed schedule.

Dated: January 27, 2016

Respectfully submitted.

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EXHIBIT A

Proposed Schedule

EVENT	Plaintiff's Proposed Date	Defendants' Proposed Date
Court holds Rule 16 Conference	2/2/16	
Parties apply for entry of protective order	2/16/16	2/16/2016
Plaintiff serves Disclosure of Asserted Claims and Infringement Contentions and accompanying document production (N.D. Cal. Local Patent Rules 3-1, 3-2)	4/1/16	4/1/2016
Defendants serve Invalidity Contentions and accompanying document production (N.D. Cal. Local Patent Rules 3-3, 3-4)	4/1/16	6/3/2016
Exchange Proposed Terms for Construction (N.D. Cal. Local Patent Rules 4-1)	5/6/16	7/1/2016
Exchange Preliminary Claim Constructions and Extrinsic Evidence (N.D. Cal. Local Patent Rules 4-2)	5/13/16	7/22/2016
File Joint Claim Construction and Prehearing Statement (N.D. Cal. Local Patent Rules 4-3)	N/A	8/19/2016
Completion of Claim Construction Discovery (N.D. Cal. Local Patent Rules 4-4)	N/A	10/14/2016
Parties simultaneously exchange Opening Claim Construction brief	5/27/16	N/A
Parties simultaneously exchange Responsive Claim Construction brief	6/15/16	N/A
Plaintiff files Opening Claim Construction Brief (N.D. Cal. Local Patent Rules 4-5(a))	N/A	11/4/2016
Defendants file Responsive Claim Construction Brief (N.D. Cal. Local Patent Rules 4-5(b))	N/A	12/2/2016
Plaintiff files Reply Claim Construction Brief (N.D. Cal. Local Patent Rules 4-5(c))	N/A	12/21/2016
Defendants file Surreply Claim Construction Brief	N/A	1/4/2017
Markman hearing	6/30/16 or Court's earliest availability thereafter	2/17/2017 or Court's earliest availability thereafter
Disclosure of any advice of counsel (N.D. Cal. Local Patent Rules 3-7)	N/A	50 days after Court's claim construction ruling

Parties substantially complete document production	6/17/16	5/5/2017
Plaintiffs provide final infringement contentions	7/29/16	N/A
Defendants provide final invalidity contentions	7/29/16	N/A
Close of fact discovery	8/26/16	8/18/2017
Parties exchange opening expert reports on subject matter for which they bear the burden of proof	9/23/16	10/6/2017
Parties exchange rebuttal expert reports	10/21/16	11/10/2017
Parties exchange reply expert reports	N/A	12/1/2017
Close of Expert Discovery	12/16/16	1/12/2018
File dispositive motions and motions to strike expert testimony	2/24/17	3/2/2018
Answer to Dispositive Motions	3/24/17	3/30/2018
Reply to Dispositive Motions	4/14/17	4/13/2018
Motions in Limine	90 days before trial	5/25/2018
Opposition to Motions in Limine	14 days after service of Motions in Limine	6/8/2018
Reply to Motions in Limine	N/A	6/15/2018
Pre-trial Brief	60 days before trial	7/13/2018
Pre-trial Conference	30 days before trial	30 days before trial
Trial	September 2017, or Court's earliest availability thereafter	September 2018, or Court's earliest availability thereafter

CERTIFICATE OF SERVICE

I hereby certify that on January 27, 2016, I caused the foregoing **JOINT REPORT OF RULE 26(f) MEETING AND PROPOSED DISCOVERY PLAN** to be filed electronically through the Court's CM/ECF system. Copies of the foregoing have been served by electronic mail via the Court's CM/ECF system on all counsel of record as follows:

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